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Registration Decision RD2011-10

Mineral Oil

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Registration Decision for Mineral Oil

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and its Regulations, is granting full registration for the sale and use of Spray Oil 10 Technical and Civitas Fungicide for Golf Course Turf, containing the technical grade active ingredient mineral oil, to control dollar spot and suppress spring leaf spot and pink and grey snow mould on golf courses, including fairways, greens, roughs and tees.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

These products were first proposed for registration in the consultation document[1] Proposed Registration Decision PRD2010-22, *Mineral Oil*. This Registration Decision[2] describes this stage of the PMRA's regulatory process for mineral oil and summarizes the Agency's decision and the reasons for it. The PMRA received no comments on PRD2010-22, *Mineral Oil*. This decision is consistent with the proposed registration decision stated in PRD2010-22, *Mineral Oil*.

For more details on the information presented in this Registration Decision, please refer to the Proposed Registration Decision PRD2010-22, *Mineral Oil* that contains a detailed evaluation of the information submitted in support of this registration.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable[3] if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its conditions of registration. The Act also requires that products have value[4] when used according to label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

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1 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

2 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

3 "Acceptable risks" as defined by subsection 2(2) of *Pest Control Products Act*.

4 "Value" as defined by subsection 2(1) of *Pest Control Products Act* ("...the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (*a*) efficacy; (*b*) effect on host organisms in connection with which it is intended to be used; and (*c*) health, safety and environmental benefits and social and economic impact.")

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (for example, children) as well as organisms in the environment (for example, those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticides and Pest Management portion of Health Canada's website at healthcanada.gc.ca/pmra.

What Is Mineral Oil?

Mineral oil is a non-conventional pesticide product currently registered to control insect pests on various crops. The oil acts as a physical barrier to pathogens.

Health Considerations

Can Approved Uses of Mineral Oil Affect Human Health?

Mineral Oil is unlikely to affect your health when used according to label directions.

Exposure to mineral oil may occur when handling and applying the end-use product, Civitas Fungicide for Golf Course Turf. When assessing health risks, two key factors are considered: the levels where no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). Only uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

The technical grade active ingredient, mineral oil, is of low acute toxicity by the oral, inhalation and dermal routes. Aliphatic solvents, such as mineral oil, are also considered to be mild eye and skin irritants, and non-sensitizing.

Residues in Water and Food

Dietary risks from food and water are not of concern.

The use for Civitas Fungicide for Golf Course Turf is as a fungicide to be applied to turf, which should, therefore, not result in additional exposure to sources of food or drinking water beyond currently registered food uses. Therefore, this use of mineral oil is not expected to result in dietary risk from consuming food or drinking water.

Occupational Risks From Handling Mineral Oil

Occupational risks are not of concern, when mineral oil is used according to label directions, which include protective measures.

There is potential for dermal and inhalation exposure to mineral oil when handling and applying Civitas Fungicide for Golf Course Turf. However, due to the low toxicity of mineral oil and the exposure mitigation measures on the label, there is no concern regarding occupational exposure to Civitas Fungicide for Golf Course Turf.

Environmental Considerations

What Happens When Mineral Oil Is Introduced Into the Environment?

Environmental risks to non-target organisms are not of concern when Mineral Oil and the end-use product, Civitas Fungicide for Golf Course Turf, are used on golf course turf according to label directions, which include precautionary label statements and buffer zones.

White Mineral Oil is currently introduced into the environment when used as an agricultural insecticide (rutabaga, pome and stone fruits, prunes, Saskatoon berries, and Highbush blueberries) and on ornamentals. The use of Civitas Fungicide for Golf Course Turf will be a major new use as a fungicide on golf course turf (USC 30).

Mineral oil is eligible for review as a non-conventional product given the characteristics that ithas low inherent toxicity to most non-target organisms; it is widely available to the public forother uses and has a long history of equivalent exposure to humans and the environment with minimal toxicity; it has a non-toxic mode of action; and it is unlikely to cause pest resistance. Therefore, only Tier 1 (acute toxicity) data are considered for the risk assessment initially.

Non-target species (for example, birds, mammals, plants, honeybees, fish, oysters, and daphnia) could be exposed to mineral oil in the environment from direct exposure of the pesticide during spraying, or from spray drift or runoff to surface water.

Mineral oil may pose a risk to some aquatic organisms. Precautionary label statements are required on the label and buffer zones are required to mitigate exposure of sensitive aquatic habitats from spray drift.

Value Considerations

What Is the Value of Civitas Fungicide for Golf Course Turf?

Civitas Fungicide for Golf Course Turf is a non-conventional fungicide that suppresses diseases on golf course turf.

There is an increasing demand for non-conventional pesticides for turf use due to pesticide bans implemented in Canada at the provincial and municipal levels. Civitas Fungicide for Golf Course Turf is a non-conventional product that is compatible with conventional pesticides and cultural methods employed to combat disease.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

The key risk-reduction measures being proposed on the label of Civitas Fungicide for Golf Course Turf to address the potential risks identified in this assessment are as follows.

Key Risk-Reduction Measures

Human Health

The statements "Keep out of reach of unauthorized personnel", "May be harmful if swallowed or inhaled", "Avoid contact with eyes, skin and clothing", "Use with adequate ventilation", and "Wash thoroughly after using" have been included in the Precautions section of the secondary display panel of the label for Civitas Fungicide for Golf Course Turf. Furthermore, the product label instructs applicators to wear chemical resistant gloves and long protective clothing during mixing, loading, application, clean-up and repair.

Additionally, the product label instructs applicators to apply only when the potential for drift to areas of human habitation or areas of human activity, such as houses, cottages, schools, and recreational areas, is minimal, and to take into consideration wind speed, wind direction, temperature, application equipment, and spray settings before applying.

Environment

Precautionary label statements are required on the label to mitigate potential runoff to aquatic systems.

To protect non-target aquatic organisms, precautionary label statements are required on the label, and Civitas Fungicide for Golf Course Turf cannot be sprayed within 1 to 5 metres of sensitive aquatic habitats. The distance required depends on the method of application and the depth of the water in the aquatic habitat.

Other Information

1. The relevant test data on which the decision is based (as referenced in PRD2010-22, *Mineral Oil*) are available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa). For more information, please contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra.infoserv@hc-sc.gc.ca).

2. Any person may file a notice of objection[5] regarding this registration decision within 60 days from the date of publication of this Registration Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticides and Pest Management portion of the Health Canada's website (Requesting a Reconsideration of Decision, healthcanada.gc.ca/pmra) or contact the PMRA's Pest Management Information Service.

[5] As per subsection 35(1) of the *Pest Control Products Act*.